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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/624,567	07/23/2003	Takatoshi Miyahara	027430.101-US01	6611

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EXAMINER

CROW, ROBERT THOMAS

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 05/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/624,567	Applicant(s) MIYAHARA ET AL.	
	Examiner Robert T. Crow	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 21 April 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
4a) Of the above claim(s) 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I in the reply filed on 21 April 2006 is acknowledged. The traversal is on the ground(s) that the search would not be burdensome. This is not found persuasive because a search of Group I would require searching bodies with depressions, covers, electrodes and voltage. In contrast, a search of Group II would require searching point mutations, electrolytes, electrochemically active molecules, and single nucleotide polymorphisms. Therefore, the searching of both Groups I and II would place undue burden on the office.

The requirement is still deemed proper and is therefore made FINAL.

Claim 12 is with drawn. Claims 13-36 were previously cancelled. Claims 1-11 are currently under prosecution.

Information Disclosure Statement

The Information Disclosure Statements filed 23 July 2003, 26 March 2004, and 1 September 2005 are acknowledged. However, only the Abstracts of documents JP-56-152958 A and JP9288080 are being considered because English translations of the remainder of the documents have not been provided. The

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documents by Hashimoto et al (Preparing for Clinical Care Analysis in the 21st Century, 16th International Symposium, 1996) and Takenaka (Business Kagaku, vol. 48, No. 12, 1999) are not being considered because no copies have been provided.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 4, 5, and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Hollis et al (U.S. Patent No. 5,653,939, issued 5 August 1997).

Regarding claim 1, Hollis et al teach the chip comprising: a body having a depression (e.g., a array semiconductor having depressed test sites; column 4, lines 35-49 and Figure 4); an upper cover to be fixed to said body from above said depression (e.g., a laser-radiation-permeable film that encloses the array; column 14, lines 39-43 and Figures 18 and 19); an enclosed internal space part, formed by said depression in said body as a result of said upper cover being fixed to said body (e.g., the laser-radiation-permeable film that encloses the array; column 14, lines 39-43 and Figures 18 and 19), capable of being filled with and being

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emptied of gene samples (e.g., a sample substance is applied [Abstract, lines 1-7] and excess samples are removed [column 4, lines 53-55] wherein genetic probes are analyzed; column 16, lines 20-42); a plurality of measuring electrodes formed at the bottom of said space part (e.g., the test sites each have an electrode; column 5, lines 40-67 and Figures 4 and 5D); and a common electrode which is a counter electrode to said measuring electrodes arranged in the space part (e.g., upper electrode 21 of Figure 4); wherein when a voltage is applied between said common electrode and said measuring electrodes, electric current between said common electrode and said measuring electrodes can be detected (e.g., electrical properties of the test sites are detected to determine hybridization; column 2, lines 30-37).

Regarding claim 3, Hollis et al teach the chip of claim 1, wherein said upper cover is transparent (e.g., the cover is a laser-radiation-permeable film that encloses the array; column 14, lines 39-43 and Figures 18 and 19).

Regarding claim 4, Hollis et al teach the chip of claim 1, wherein said measuring electrodes form an electrode array (Abstract).

Regarding claim 5, Hollis et al teach the chip of claim 1, wherein said common electrode is arranged so as not to contact the measuring electrodes (e.g., the upper electrode 21 of Figure 4 is separate from the electrodes in the wells).

Regarding claim 7, Hollis et al teach the chip of claim 1, wherein each of said plurality of measuring electrodes is combined with each of a plurality of

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wirings; and wherein said wirings form a matrix structure as a grid wiring consisting of a plurality of conductors fixed in rows and lines to connect each of said measuring electrodes arranged in the array with their respective nearest conductor of the conductors fixed in rows and lines (column 5, lines 10-23 and Figure 1).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

2. Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilding et al (U.S. Patent No. 5,587,128, issued 24 December 1996) in view of Hollis et al (U.S. Patent No. 5,653,939, issued 5 August 1997).

Regarding claim 1, Wilding et al teach a chip comprising: a body having a depression (Figure 2B); an upper cover to be fixed to said body from above said depression (Figure 2B); an enclosed internal space part, formed by said depression in said body as a result of said upper cover being fixed to said body (e.g., the device is sealed by the cover; column 4, lines 15-20 and Figure 2B), capable of being filled with and being emptied of gene samples (e.g., the device tests for the presence of a gene [column 4, lines 1-3], and samples are introduced and products are withdrawn from the device; column 16, lines 30-40). While Wilding et al also teach the device with a plurality of electrodes (column 20, lines 57-59) and electrical detection of nucleic acids (e.g., the presence of polynucleotides is detected by measuring conductivity; column 21, lines 15-20); Wilding et al do not specifically teach either a counter-electrode nor an array of electrodes.

However, Hollis et al teach the chip comprising: an enclosed internal space part, formed by said depression in said body as a result of said upper cover being fixed to said body (e.g., the laser-radiation-permeable film that encloses the array; column 14, lines 39-43 and Figures 18 and 19), capable of

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being filled with and being emptied of gene samples (e.g., a sample substance is applied [Abstract, lines 1-7] and excess samples are removed [column 4, lines 53-55] wherein genetic probes are analyzed; column 16, lines 20-42); a plurality of measuring electrodes formed at the bottom of said space part (e.g., the test sites each have an electrode; column 5, lines 40-67 and Figures 4 and 5D); and a common electrode which is a counter electrode to said measuring electrodes arranged in the space part (e.g., upper electrode 21 of Figure 4); wherein when a voltage is applied between said common electrode and said measuring electrodes, electric current between said common electrode and said measuring electrodes can be detected (e.g., electrical properties of the test sites are detected to determine hybridization; column 2, lines 30-37) with the added advantage that the uniform electrical properties of the device enhance the detection sensitivity beyond many other approaches (column 19, lines 20-27)

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was claimed to have modified the electrode-bearing chip of Wilding et al with the counter-electrode and electrode array as taught by Hollis et al with a reasonable expectation of success. The ordinary artisan would have been motivated to make such a modification because said modification would have resulted in enhancement of detection sensitivity beyond many other approaches as explicitly taught by Hollis et al (column 19, lines 20-27)

Regarding claim 2, the chip of claim 1 is discussed above. Wilding et al also teach opposing surfaces having injection holes extending to the depression of the body (e.g., the two injection ports 16 in Figure 2A, which are on opposite ends of the device; column 16, lines 26-46). While Wilding et al do not specifically teach the injection holes on two opposing surface of each of said body and said upper cover, the courts have held that the rearrangement of parts within a device is obvious when the arrangement does not specifically modify the operation of the device (*In re Japikse*, 181 F.2d 1019, 86 USPQ 70 (CCPA 1950)). See MPEP §2144.04.

Regarding claim 3, the chip of claim 1 is discussed above. Wilding et al also teach transparent covers (column 4, lines 17-20).

Regarding claim 4, the chip of claim 1 is discussed above. Hollis et al also teach said measuring electrodes form an electrode array (Abstract).

Regarding claim 5, the chip of claim 1 is discussed above. Hollis et al also teach said common electrode is arranged so as not to contact the measuring electrodes (e.g., the upper electrode 21 of Figure 4 is separate from the electrodes in the wells).

Regarding claim 6, the chip of claim 1 is discussed above. Wilding et al also teach immobilization of PCR products (e.g., a detection chamber has immobilized probes for hybridizing to PCR products; column 20, lines 20-41).

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Hollis et al teach the immobilization of nucleic acids to electrodes (i.e., microlocations; column 4, lines 47-59).

Regarding claim 7, the chip of claim 1 is discussed above. Hollis et al also teach each of said plurality of measuring electrodes is combined with each of a plurality of wirings; and wherein said wirings form a matrix structure as a grid wiring consisting of a plurality of conductors fixed in rows and lines to connect each of said measuring electrodes arranged in the array with their respective nearest conductor of the conductors fixed in rows and lines (column 5, lines 10-23 and Figure 1).

Regarding claim 8, the chip of claim 1 is discussed above. Wilding et al also teach said chip is configured to be inserted and removed from a measuring apparatus capable of detecting an electric current, and is configured to be electrically connected to said measuring apparatus capable of detecting an electric current and is configured to be electrically connected to said measuring apparatus (e.g., the chip is inserted in an appliance for detecting the contents of the device [column 19, lines 15-37 and Figures 17 and 18], wherein movement of fluid samples are monitored by the appliance [column 19, lines 35-37], and wherein the presence of polynucleotides is detected by measuring conductivity; column 21, lines 15-20).

Regarding claim 9, the chip of claim 1 is discussed above. Wilding et al also teach said chip forms part of a card or cassette (e.g., the chip is inserted in an appliance for detecting the contents of the device; column 19, lines 15-37 and Figures 17 and 18).

Regarding claim 10, the chip of claim 1 is discussed above. Wilding et al also teach a measuring apparatus capable of detecting and analyzing genes wherein said chip is configured to be inserted and removed from said measuring apparatus, and is configured to be electrically connected to said measuring apparatus (e.g., the chip is inserted in an appliance for detecting the contents of the device [column 19, lines 15-37 and Figures 17 and 18], wherein movement of fluid samples are monitored by the appliance [column 19, lines 35-37], and wherein the presence of polynucleotides is detected by measuring conductivity; column 21, lines 15-20).

Regarding claim 11, the apparatus of claim 10 is discussed above. Wilding et al also teach the temperature of said chip is changed by using Peltier devices to control temperature conditions for hybridization (column 16, lines 47-60).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-6 and 8-11 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5, 7, 11-13, and 16-22 of U.S. Patent No. 6,916,614 in view of Wilding et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to chips having electrodes within depressions (i.e., the pin electrodes of the '614 claims are within a recess of a frame), counter-electrodes, immobilized nucleic acids, Peltier elements, and chips

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loaded into apparatuses. The claims of the '614 patent are silent with respect to covers.

However, Wilding et al teach chips and apparatuses comprising: a body having a depression (Figure 2B) and an upper cover to be fixed to said body from above said depression (Figure 2B) with the added advantage that the cover seals the reaction chamber during reactions (column 4, lines 15-20).

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was claimed to have modified the chips and apparatuses of the '614 claims with the cover as taught by Wilding et al with a reasonable expectation of success. The ordinary artisan would have been motivated to make such a modification because said modification would have resulted in sealing of the reaction chamber during reactions as explicitly taught by Wilding et al (column 4, lines 15-20).

Conclusion


No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert T. Crow whose telephone number is (571) 272-1113. The examiner can normally be reached on Monday through Friday from 8:00 am to 4:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


5/15/06

Robert T. Crow
Examiner
Art Unit 1634


**BJ FORMAN, PH.D.
PRIMARY EXAMINER**